

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION**

**TRUDELL MEDICAL INTERNATIONAL**

*Plaintiff,*

**V.**

**RPC FORMATEC GMBH,**

***Defendant.***

[illegible]

**Case No.: 1:14-cv-032**

## JURY TRIAL DEMANDED

## **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Trudell Medical International (“Trudell”), brings this Complaint against RPC Formatec GmbH (“RPC”). As its complaint against RPC, Trudell states and alleges as follows:

## NATURE OF THE ACTION

1. This is an action for monetary relief to recover for the damage caused by and to prevent further damage arising from the unlawful and unauthorized use of Trudell's intellectual property through the infringement of Trudell's patents under 35 U.S.C. § 271 by the Defendant. Specifically, Trudell complains that the Defendant infringes at least claims 11 and 21 of Trudell's U.S. Patent No. 8,505,773 (the "773 Patent") and at least claims 9 and 19 of Trudell's U.S. Patent No. 8,662,075 (the "075 Patent").

## THE PARTIES

2. Trudell is a partnership organized under the laws of the Province of Ontario, Canada, and has a place of business at 725 Third Street, London Ontario, Canada N5VG4.

3. Trudell researches, develops, manufactures, markets, and sells medical devices, including devices intended for use with metered dose inhalers, such as dose counters.

4. Trudell is the assignee of the '773 Patent, a true and correct copy of which is attached as Exhibit A. The '773 Patent was legally issued on August 13, 2013, and is directed to an indicating device. Trudell is the owner of all right, title, and interest in the '773 Patent, including the right to sue and recover damages for infringement of the '773 Patent by virtue of the assignments recorded at Reel/Frame Number 031886/0902 and 031886/0969.

5. Trudell is the assignee of the '075 Patent, a true and correct copy of which is attached as Exhibit B. The '075 Patent was legally issued on March 4, 2014, and is directed to an indicating device. Trudell is the owner of all right, title, and interest in the '075 Patent, including the right to sue and recover damages for infringement of the '075 Patent by virtue of the assignments recorded at Reel/Frame Number 009545/0340, 009903/0881, and 015972/0044.

6. On information and belief, RPC is a German company with a principal place of business at Stockheimer Strasse 30, Mellrichstadt, 97678, Germany.

7. On information and belief, RPC is a company that designs and develops inhalation systems and mouthpieces and that manufactures, uses, offers to sell, sells, and/or imports dose indicator devices that are or can be used with Pressurized Metered Dose Inhalers (pMDIs) to indicate the number of actuations used or remaining in a pMDI of pharmaceutical medicament, and/or directly causes others to engage in such conduct, within the United States and, in particular, in this District.

**JURISDICTION AND VENUE**

8. This is an action for patent infringement under 35 U.S.C. § 271. This Court has subject matter jurisdiction over Trudell's federal claims of patent infringement pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, RPC manufactures infringing products that are offered for sale, sold, and are purposefully directed to and imported into Virginia and this judicial district for sale by pharmaceutical companies. On information and belief, RPC derives substantial revenue from offering for sale, selling, and/or importing its infringing products into Virginia and in this district. On information and belief, RPC ships its infringing products into this judicial district through the Norfolk, Virginia shipping port for delivery to Boehringer Ingelheim.

10. This Court has personal jurisdiction over RPC pursuant to provisions of the Virginia Long Arm Statute, Va. Code. Ann. § 8.01-328.1, and the laws of the United States based at least on RPC having committed a tortious injury in this Commonwealth by purposefully shipping infringing products into this judicial district through an established distribution channel and through ongoing shipments to this judicial district resulting in substantial revenue to RPC.

11. Venue is proper in this District under 28 U.S.C. §§ 1391 (b) and (c) and Local Rule 3(c).

**COUNT I: PATENT INFRINGEMENT OF THE '773 PATENT**

12. Trudell incorporates by reference each of the preceding allegations of paragraphs 1 - 11 above as though stated herein.

13. On information and belief, RPC offers for sale, sells, uses and/or imports, in the United States dose indicator metering mechanisms that are or can be integrated into pMDI actuators, including but not limited to pMDI actuator mouthpieces used in conjunction with

Atrovent® HFA that is distributed by Boehringer Ingelheim (hereinafter the “infringing product”), and these activities infringe at least claims 11 and 21 of the ’773 Patent in violation of 35 U.S.C. § 271.

14. On information and belief, RPC offers for sale and sells the infringing product to Boehringer Ingelheim for delivery to and use in the United States.

15. On information and belief, RPC imports the infringing product into the United States through a Norfolk, Virginia shipping port for distribution to Boehringer Ingelheim.

16. On information and belief, the infringing product is included in Boehringer Ingelheim’s Atrovent® HFA inhalation aerosol mouthpiece that is offered for sale and sold to end-users in this District for use by the end-user in maintenance treatment of bronchospasms associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

17. RPC’s infringing product counts actuations of a pMDI medicament canister for indicating a number of metered dosages of the medicament dispensed from the canister.

18. RPC’s infringing product includes an indicator housing having a longitudinally extending cavity adapted to receive a support block extending from a dispenser housing, where the cavity defines a longitudinal axis.

19. RPC’s infringing product includes an actuator with a central, cylindrical hub portion adapted to be engaged by a container disposed in the dispenser housing, the cylindrical hub portion centered about the longitudinal axis, where the actuator is moveable along the longitudinal axis relative to the indicator housing, the actuator comprising a resilient arm.

20. RPC's infringing product includes a drive gear rotatably disposed in the indicator housing, where the drive gear is rotatable in response to successive engagements by the resilient arm of the actuator.

21. RPC's infringing product includes an indicator rotatably disposed in the indicator housing, where the indicator is rotatable in response to the rotation of the drive gear, the indicator comprising dosage indicia.

22. On information and belief, RPC has induced infringement of the '773 Patent within this District, and elsewhere within the United States, by its intentional acts which have successfully, among other things, encouraged, instructed, enabled, and otherwise caused others, such as Boehringer Ingelheim, physicians, or patients, to use the infringing product to dispense metered dosages of medicament from a container of medicament, such as Boehringer Ingelheim's Atrovent® HFA. RPC has provided the infringing product to said others for the primary purpose of causing infringing acts by said others. RPC had knowledge that the infringing product infringes the '773 Patent at least as early as January 13, 2014. On information and belief, RPC has specifically intended that said others use the infringing product in such a way that the '773 Patent is infringed by, at minimum, supplying an infringing product that works with a medicament container such that it infringes the '773 Patent. On information and belief, Defendants knew that their actions, including but not limited to supplying the infringing product, would induce infringement by said others. On information and belief, said others use the infringing product to infringe the '773 Patent.

23. On information and belief, RPC has contributorily infringed the '773 Patent within this District, and elsewhere within the United States, by offering to sell, selling, or importing the infringing product into the United States as a component for use in infringing the

'773 Patent. On information and belief, the infringing product is a material component required to infringe the '773 Patent. On information and belief, metered dosages of Boehringer Ingelheim's Atrovent® HFA medicament cannot be dispensed to patients without the infringing product. RPC had knowledge that the infringing product infringes the '773 Patent at least as early as January 13, 2014. On information and belief, RPC had knowledge that the infringing product was especially made for use in infringing the '773 Patent. On information and belief, RPC specifically supplies the infringing product to be used in dispensing metered dosages of medicament from a container of medicament. On information and belief, RPC had knowledge that the infringing product is not a staple article suitable for substantial non-infringing use. On information and belief, the infringing product is specifically intended to be used with Boehringer Ingelheim's Atrovent® HFA medicament container.

24. Should RPC's conduct infringing the '773 Patent continue after service of this complaint, then said conduct would be willful and entitle Trudell to enhanced damages and attorney's fees.

25. On information and belief, RPC's infringing activities have caused and will continue to cause Trudell irreparable injury unless and until enjoined by this Court.

26. As a result of RPC's infringing activities, Trudell has suffered and will continue to suffer damages in an amount yet to be determined. Under 35 U.S.C. §§ 283 and 284, Trudell is entitled to recover damages, as well as permanent injunctive relief against further infringing activity.

#### **COUNT II: PATENT INFRINGEMENT OF THE '075 PATENT**

27. Trudell incorporates by reference each of the preceding allegations of paragraphs 1 - 11 above as though stated herein.

28. On information and belief, RPC offers for sale, sells, uses and/or imports, in the United States dose indicator metering mechanisms that are or can be integrated into pMDI actuators, including but not limited to pMDI actuator mouthpieces used in conjunction with the infringing product, and these activities infringe at least claims 9 and 19 of the '075 Patent in violation of 35 U.S.C. § 271.

29. On information and belief, RPC offers for sale and sells the infringing product to Boehringer Ingelheim for delivery to and use in the United States.

30. On information and belief, RPC imports the infringing product into the United States through a Norfolk, Virginia shipping port for distribution to Boehringer Ingelheim.

31. On information and belief, the infringing product is included in Boehringer Ingelheim's Atrovent® HFA inhalation aerosol mouthpiece that is offered for sale and sold to end-users in this District for use by the end-user in maintenance treatment of bronchospasms associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

32. RPC's infringing product counts actuations of a pMDI medicament canister for indicating a number of metered dosages of the medicament dispensed from the canister.

33. RPC's infringing product includes a housing with a first annular wall radially spaced around a longitudinal axis and defining an interior cavity, where the first annular wall includes a viewing window.

34. RPC's infringing product includes a single indicator member rotatably mounted in the housing about the longitudinal axis, where the single indicator member has a second annular wall radially spaced around the longitudinal axis where the single indicator is nested in the interior cavity of the housing, and where the second annular wall has an outer circumferential

surface visible through the viewing window and has dosage indicia adapted to indicate the number of dosages of medicament dispensed from or remaining in the container.

35. RPC's infringing product includes an actuator reciprocally moveable relative to the housing along the longitudinal axis.

36. RPC's infringing product includes a drive mechanism intermittently engageable with the single indicator member, where the drive mechanism is operable to advance the single indicator member an incremental amount when the drive mechanism is engaged with the single indicator member, and where the single indicator member remains stationary and is free of engagement from the drive mechanism for at least some of the reciprocal movements of the actuator.

37. On information and belief, RPC has induced infringement of the '075 Patent within this District, and elsewhere within the United States, by its intentional acts which have successfully, among other things, encouraged, instructed, enabled, and otherwise caused others, such as Boehringer Ingelheim, physicians, or patients, to use the infringing product to dispense a medicament from a container, such as Boehringer Ingelheim's Atrovent® HFA. RPC has provided the infringing product to said others for the primary purpose of causing infringing acts by said others. RPC had knowledge that the infringing product infringes the '075 Patent at least as early as March 4, 2014. On information and belief, RPC has specifically intended that said others use the infringing product in such a way that the '075 Patent is infringed by, at minimum, supplying an infringing product that works with a medicament container such that it infringes the '075 Patent. On information and belief, Defendants knew that their actions, including but not limited to designing the infringing product, would induce infringement by said others. On information and belief, said others use the infringing product to infringe the '075 Patent.



38. On information and belief, RPC has contributorily infringed the '075 Patent within this District, and elsewhere within the United States, by offering to sell, selling, or importing the infringing product into the United States as a component for use in infringing the '075 Patent. On information and belief, the infringing product is a material component required to infringe the '075 Patent. On information and belief, Boehringer Ingelheim's Atrovent® HFA medicament cannot be dispensed to patients without the infringing product. RPC had knowledge that the infringing product infringes the '075 Patent at least as early as March 4, 2014. On information and belief, RPC had knowledge that the infringing product was especially made for use in infringing the '075 Patent. On information and belief, RPC specifically supplies the infringing product to be used in dispensing medicament from a container of medicament. On information and belief, RPC had knowledge that the infringing product is not a staple article suitable for substantial non-infringing use. On information and belief, the infringing product is specifically intended to be used with Boehringer Ingelheim's Atrovent® HFA medicament container.

39. Should RPC's conduct infringing the '075 Patent continue after service of this complaint, then said conduct would be willful and entitle Trudell to enhanced damages and attorney's fees.

40. On information and belief, RPC's infringing activities have caused and will continue to cause Trudell irreparable injury unless and until enjoined by this Court.

41. As a result of RPC's infringing activities, Trudell has suffered and will continue to suffer damages in an amount yet to be determined. Under 35 U.S.C. §§ 283 and 284, Trudell is entitled to recover damages, as well as permanent injunctive relief against further infringing activity.

**PRAYER FOR RELIEF**

**WHEREFORE**, Trudell respectfully requests this Court to enter a judgment that:

- A. United States Patent No. 8,505,773 be adjudged by this Court to be enforceable and not invalid;
- B. RPC be adjudged by this Court to have infringed U.S. Patent No. 8,505,773;
- C. RPC be adjudged by this Court to have induced infringement of U.S. Patent No. 8,505,773;
- D. RPC be adjudged by this Court to have contributorily infringed U.S. Patent No. 8,505,773;
- E. RPC, and the directors, officers, agents, servants, and employees, and those acting in concert or participation with RPC be permanently enjoined from further infringement of U.S. Patent No. 8,505,773;
- F. United States Patent No. 8,662,075 be adjudged by this Court to be enforceable and not invalid;
- G. RPC be adjudged by this Court to have infringed U.S. Patent No. 8,662,075;
- H. RPC be adjudged by this Court to have induced infringement of U.S. Patent No. 8,662,075;
- I. RPC be adjudged by this Court to have contributorily infringed U.S. Patent No. 8,662,075;
- J. RPC, and the directors, officers, agents, servants, and employees, and those acting in concert or participation with RPC be permanently enjoined from further infringement of U.S. Patent No. 8,662,075;

K. RPC be ordered by this Court to account for and pay Trudell damages adequate to compensate Trudell for the infringement that has occurred, but in no event less than a reasonable royalty, as permitted by 35 U.S.C. § 284, together with pre and post-judgment interest and costs as fixed by the Court;

L. This case be deemed exceptional and Trudell be awarded its costs, expenses and reasonable attorneys' fees as provided by 35 U.S.C. § 285; and

M. Trudell be awarded such other and further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Fed. R. Civ. P. 38(b) and Local Rule 38, Trudell demands a trial by jury in this action on all issues triable by jury.

March 10, 2014.

Respectfully Submitted,

TRUDELL MEDICAL INTERNATIONAL

/s/

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 10<sup>th</sup> day of March, 2014, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to all counsel of record, and I further certify that I will serve a copy of the foregoing by email and Federal Express on:

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/s/

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